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Prevention

RENAL SYMPATHETIC DENERVATION FOR TREATMENT OF RESISTANT HYPERTENSION: TWO-YEAR UPDATE FROM THE SYMPLICITY HTN-2 RANDOMIZED CONTROLLED TRIAL

Oral Contributions
North, Room 121
Sunday, March 10, 2013, 9:15 a.m.-9:30 a.m.

Session Title: Prevention: Blood Pressure - Hot Topics for 2013
Abstract Category: 1. Acute Coronary Syndromes: Clinical
Presentation Number: 918-8

Authors: *Murray Esler, Henry Krum, Roland Schmieder, Michael Bohm, Baker IDI Heart and Diabetes Institute, Melbourne, Australia*

Background: Radiofrequency ablation of renal artery nerves has been shown to reduce blood pressure (BP) in patients with severe, treatment-resistant hypertension (rHTN, BP uncontrolled on at least 3 antihypertensive drugs). Longer follow-up of subjects undergoing renal denervation (RDN) is essential to establish the long-term safety and reliability of this novel treatment intervention.

Methods: The Symplicity™ HTN-2 trial randomized subjects with rHTN and systolic BP ≥160 mm Hg to treatment by RDN or to maintenance on prior therapy. Control subjects were eligible to crossover to RDN at 6 months. All subjects were followed for 2 years (18 months post-RDN for crossover patients) to assess long-term effectiveness and safety of RDN.

Results: At baseline, more crossover than RDN subjects were female (60% vs 35%), and 40% of the RDN and 30 % of the crossover group subjects had type 2 diabetes. BP was significantly lower than baseline at each time point (table). Pulse pressure was reduced -18.5 in the RDN group at 24 months and -17.6 in the crossover group at 18 month ($p<0.01$ for both). Heart rate was reduced by renal denervation (table), presumably due to central sympathetic inhibition from afferent nerve ablation. No device-related serious adverse events occurred.

Conclusions: RDN with the Symplicity catheter consistently reduced systolic BP by 28-32 mm Hg over 2 years with no safety concerns.

Office BP (mm Hg)	Initial RDN	Cross-over to RDN	Heart Rate (bpm)	Initial RDN	Cross-over to RDN
Pre-procedure baseline† Systolic BP Diastolic BP	(n=52) 178.2±17.7 97.0±15.8	(n=37) 190.9±19.6 101.4±16.2	Pre-procedure baseline†	(n=52) 74.7 ± 14.9	(n=37) 71.8 ± 15.3
6 mo. Δ from baseline Systolic BP Diastolic BP	(n=49) -31.7 ± 23.1 -11.7 ± 11.2	(n=35) -23.7 ± 27.5 -8.4 ± 12.1	6 mo. Δ from baseline	(n=49) -4.9 ± 10.2 p<0.01	(n=35) -2.6 ± 13.9 P=0.28
12 mo. Δ from baseline Systolic BP Diastolic BP	(n=47) -28.1 ± 24.9 -9.7 ± 10.6	(n=33) -23.8 ± 30.5 -9.99 ± 12.4	12 mo. Δ from baseline	(n=47) -5.0 ± 9.0 p<0.01	(n=33) -6.4 ± 13.1 p<0.01
18 mo Δ from baseline Systolic BP Diastolic BP	(n=43) -32.3 ± 26.1 -12.5 ± 13.2	(n=31) -28.4 ± 32.4 -10.8 ± 12.2	18 mo Δ from baseline	(n=43) -5.2 ± 13.6 p=0.02	(n=31) -1.8 ± 9.0 p=0.27
24 mo Δ from baseline Systolic BP Diastolic BP	(n=40) -28.87 ± 21.6 -10.4 ± 11.2	N/A	24 mo Δ from baseline	(n=40) -4.3 ± 12.3 p=0.03	N/A

p<0.01for all BP changes from baseline; †Crossover group pre-procedure baseline is at 6 months post randomization